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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,010	02/28/2002	Toru Nishihara	8279.359USWO	5759

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EXAMINER

KOSAR, ANDREW D

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/070,010	Applicant(s) NISHIHARA ET AL.	
	Examiner Andrew D Kosar	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Amendments to the specification, abstract, and claims have been entered as filed on October 26, 2004.

Priority

Applicant is advised that the Priority Document JP 2000-195804 and Certified English Translation of JP 2000-195804 have been placed in the file.

Status of the Claims

Claims 1-17 have been cancelled. New claims 18-42 are pending and have been examined on the merits.

Claims 18-42 are rejected.

Withdrawn Rejections

Rejection(s) of claims 1-17 under 35 USC §§ 102, 103, and 112 have been withdrawn, as the rejections are moot in view of the cancellation of said claims.

It is noted that claims 1-6 and 10-16 were rejected under 35 USC 102(b) in view of Kломann, not under 35 USC 102(a) as indicated in Applicants response.

Claim Objections

While it is clear what Applicant is claiming, claim 34 is objected to because the claim is grammatically confusing. The claims are drawn to a composition packaged in a container, however the final statement appears to change the scope of the claim to that of a product-by-process. Applicant is suggested to amend the claim to recite, "...

polypropylene, wherein the space between the container and package is filled with oxygen."

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 18-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kломann¹ in view of Teijin² and in view of WO 99/49991³. In the interest of compact prosecution, US 2002/0176947 ('947), a Divisional Application from the National Stage of said WO document, is used herein as an English equivalent. It is noted that the rejection is also proper relying upon '947 using the 102(e) date, which is the international filing date (*See MPEP §§ 2136.02 and 2136.03*).

The instant claims are directed towards an ophthalmic composition packed in a plastic container. The ophthalmic composition is oxygenated and the container is made of plastic with low oxygen permeability. The container is described according to the oxygen permeability as tested under specific conditions. The container is not specifically identified by dimension and/or physical characteristics (i.e.- shape, thickness of walls, having a screw-cap top, etc.). As dependent claims 22 and 23 recite specific polymers, it is the Examiners position that a teaching of polyethylene naphthalate (PEN) or polyethylene terephthalate (PET) as a plastic bottle would intrinsically possess the oxygen permeability characteristics as recited in instant claim 18.

¹ Cited in previous Office Action.

The teachings of Klomann are directed towards the ophthalmic solution and the teachings of Teijin and '947 are directed towards the container.

Klomann teaches:

1. Artificial tear fluids can obtain a "maximally possible high enrichment with oxygen or oxygenation (e.g., 50 mg of O₂ per liter)." (English Translation Page 2, 3rd paragraph)
2. That the concentration of oxygen present in the ophthalmic solution (i.e.- "artificial tears") is sufficient to treat an ophthalmological disease which is caused by oxygen deficiency, exemplified as conjunctiva of the eyeball. (Claims 1 and 2)
3. An oxygen concentration of, i.e.- 50 mg O₂/liter, and that the concentration is sufficient to treat an opthamological disease. (Claim 2)
4. The use of the recited ophthalmic solution as eye drops. (English Translation Page 4, 2nd paragraph)
5. The use of Ringer's solution as a suitable mode of oxygen delivery. (Page 3, last paragraph)
6. The use of a dropper vial, which is usually polyethylene (PE). (Claim 2)

The oxygen saturation in Klomann anticipates the claimed ranges for the ophthalmic solution. Klomann does not teach the PET or PEN container as recited in the instant claims.

'947 teaches:

² Teijin Annual Report 1997.

1. "A container such as a bottle or flask, made heterogeneously from a material with a barrier effect and a polymer material". The "barrier is an amorphous carbon material with a polymer tendency which is applied as a coating on a substrate of polymer material". (Claim 1)
 2. The "polymer material is a polyolefin or a polyester, in particular PET or PEN". (Claim 6)
 3. That PET is not impermeable to certain gases, particularly oxygen and carbon dioxide. (Page 1, [0002])
 4. Oxygen in the air is able to penetrate the polymer material (PET, *vide infra*) to come into contact with the liquid in the container (Page 1, [0004])
- '947 is using PET or PEN as a polymer for a container. The teachings of '947 do not describe the rate of gas transfer as in the instant claims.

Teijin teaches:

1. PET Resin for Bottles are, "[h]ighly transparent, strong, and impermeable to gas. Typically applied to PET bottles, and increasingly used for storage containers." (Page 33, *Principal Products*)
2. "PEN is a transparent resin with properties of excellent gas barrier, anti-hydrolysis, heat resistance and ultra violet shielding. PEN has been under development for applications to refillable bottles and others." (Page 33, *Principal Products*)

³ PCT/FR99/00692 D. Darras, et al. Published October 7, 1999.

Because the USPTO lacks testing facilities, it is the Examiner's position that the PET and/or PEN polymer used in the container of '947 and in Teijin would intrinsically possess the low oxygen permeability when tested under the conditions presented in the instant claims, in the absence of sufficient, substantial, and credible evidence to the contrary.

It would have been obvious to one of ordinary skill in the art to have used the PET or PEN bottle of '947 to store the oxygenated ophthalmic solution of Klomann with the expectation that oxygen loss from the solution would be reduced. One would have been motivated to store the ophthalmic solution in an oxygen impermeable container to reduce oxygen loss and maintain a maximal level of oxygenation in the solution. One would have a reasonable expectation for success in reducing oxygen loss from the solution during prolonged storage, as Teijin teaches that PET and PEN are both used in bottles and are impermeable to gas and an excellent gas barrier, respectively.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 18-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klomann in view of '947 and Taijin, as applied to claims 18-24 above, and further in view of US Patent 4,452,818 ('818)⁴.

⁴ Cited in previous Office Action as Haidt.

Instant claims 25 and 26 are further drawn to the ophthalmic composition wherein the composition oxygen donor is an oxygen carrier comprising a captured oxygen and the oxygen carrier is a fluorocarbon.

The teachings and motivation to combine Klomann, '947, and Taijin are discussed *supra*. The composition of Klomann does not teach a fluorocarbon.

'818 teaches:

1. A method for treating the eyes and providing lubrication with a composition comprising a perfluorocarbon or substituted derivative thereof having oxygen carrying properties in an amount sufficient to act as a lubricant. (Claim 1)
2. The composition is dispersed across the corneal and conjunctival surfaces of the eye. (Claim 7)
3. The composition is applied prior to inserting contact lenses or applied directly to the contact lenses. (Claims 10 and 11)
4. "[T]he external surfaces of the eye will be better oxygenated because of the perfluorocarbon's high diffusion properties for oxygen and carbon dioxide." (column 3, line 65+)
5. Liquid perfluorocarbons and substituted derivatives thereof have been found to be useful as a therapeutic agent or vehicle in extraocular ophthalmic preparations. (column 3, line 10+)

Because of the 'open' language of the instantly claimed composition ("the composition contains ..."), it does not exclude the presence of additional components.

Art Unit: 1654

Therefore, because Klomann teaches an ophthalmic composition for treating eye maladies and '818 teaches a therapeutic perfluorocarbon ophthalmic composition it is *prima facie* obvious to combine the two compositions in making a third composition useful as an therapeutic in eye maladies.

As set forth in *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980), "It is *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; the idea of combining them flows logically from their having been individually taught in prior art."

Further, it would have been obvious to one of ordinary skill in the art to combine the oxygen carrying properties of the perfluorocarbon in Haidt with the oxygen enriching method in Klomann in order to achieve the highest concentration of oxygen carrying capacity for a more effective method of treatment for ophthalmologic diseases of the eye resulting from oxygen deficiency.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 18-25 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kломann in view of '947 and Taijin, as applied to claims 18-24 above, and further in view of US Patent 5,389,383 ('383)⁵.

Instant claim 27 is further drawn to the ophthalmic composition wherein the oxygen carrier is a porphyrin or porphyrin containing compound.

The teachings and motivation to combine Kломann, '947, and Taijin are discussed *supra*. Kломann does not teach the use of oxygen donors/carriers, such as porphyrins and related polymers.

'383 teaches:

1. A composition for preventing or treating hypoxia-associated ocular complications through administration of a heme oxygenase inducer and an osmoprotectant in a physiologically acceptable buffer. (Claim 18)
2. That heme oxygenase inducers are any compound known to induce heme oxygenase in vivo, exemplified as heme derivates, porphyrins and porphyrin derivatives. (column 3, line 50+)

Because of the 'open' language of the instantly claimed composition ("the composition contains ..."), it does not exclude the presence of additional components. Therefore, because Kломann teaches an ophthalmic composition for treating eye maladies and '383 teaches a therapeutic ophthalmic composition for ocular (eye) complications it is *prima facie* obvious to combine the two compositions in making a third composition useful as an therapeutic in eye maladies.

⁵ Cited in previous Office Action as Huth.

As set forth in *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980), "It is *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; the idea of combining them flows logically from their having been individually taught in prior art."

Further, it would have been obvious to one of ordinary skill in the art to combine the oxygen carrying properties of the porphyrins in Huth with the oxygen enriching method in Klomann in order to maximize the capacity of oxygen in the therapeutic composition. Further one would be motivated to create a therapeutic that could be degraded naturally by such enzymes as heme oxygenase, which is both endogenous to the eye and is capable of liberating porphyrin bound oxygen.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 18-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klomann in view of '947 and Taijin, '818, and '383, as applied to claims 18-27, and in further view of WO99/21527⁶. In the interest of compact prosecution, US Patent 6,764,481 B1 ('481), the National Stage of said WO document, is used herein as an English equivalent. It is noted that the rejection is also proper relying upon '481 using

⁶ PCT/JP98/04814 Katsuhiko, et al. Published May 6, 1999.

the 102(e) date, which is the international filing date (See MPEP §§ 2136.02 and 2136.03).

Instant claims 28 to 38 are drawn to the same composition(s) as in instant claims 18-27, however the composition is now inside a container which is encased in a package. The container is not indicated as being gas-permeable or -impermeable. The container is not defined by any shape, form, or property, and therefore may be of any shape and of any oxygen permeability. In one embodiment the inner container is gas-permeable and the void space is filled with oxygen.

The teachings and 'motivation to combine' the composition are set forth *supra* and are incorporated herein.

'481 teaches:

1. A packaged ocular irrigating solution bag which comprises a gas-permeable plastic multiple compartment bag and a gas-impermeable plastic packing member for packaging the bag (Abstract).
2. The bag of the invention, the gas-permeable bag may be made from polyethylene (PE), ethylene-vinyl acetate copolymer (EVA), polypropylene (PP), polyvinyl chloride (PC), or the like and that there is no limitation to the shape or size. (column 8, line 7+)
3. The gas-impermeable packaging can be made from PET, PEN, polyvinyl alcohol (PVA), ethylene-vinyl alcohol copolymer (EVOH), polyvinylidene chloride (PVDC), and nylon, and that there is no limitation on the size or shape. (column 8, line 38+)

The Examiner notes that (2) relates to the instantly claimed 'container' and (3) relates to the instantly claimed 'package'.

With regards to the PET and PEN, the Examiner's position is stated *supra* and incorporated herein.

The teachings of '481 provide for the space between the inner and outer bag to be filled with a gasses, specifically carbon dioxide and air or carbon dioxide and nitrogen, to maintain the proper pH for the ocular solution(s).

First, since Klomann teaches a container made of PE, it would have been obvious to use the container of Klomann as the inner component of the invention of '481, as '481 teaches that the gas-permeable bag can be of any shape or size and may be made from PE. One would have been motivated to use the Klomann PE container with a reasonable expectation in success in making a storage-stable package, as '481 states the gas-permeable bag may be of any shape or size and that it may be made of PE. Further, both containers are disclosed as used for ophthalmic purposes.

Second, In view of the beneficial teachings of Taijin, *supra*, it would have been obvious to one of ordinary skill in the art to select either PET or PEN as the impermeable outer barrier in a container-package system, to encase the PE container of Klomann, which contains the ophthalmic compositions, with the expectation that oxygen loss from the composition would be reduced and that the composition would maintain a maximal stable oxygen content for prolonged storage. One would have been motivated to encase the PE container of Klomann with the PET or PEN bag of '481 with

Art Unit: 1654

a reasonable expectation for success in reducing the loss of oxygen, increasing the storage shelf-life, and in packaging the composition for storage and sale.

Further, although '481 does not teach the use of the oxygenated compounds in the container-package system or having the void space filled with oxygen, it would have been obvious to one of ordinary skill in the art to replace the void-space gas with oxygen when storing an oxygen-rich composition with the expectation of maintaining the composition oxygen concentration. One would have been motivated to replace the gas with oxygen when storing an oxygen-rich composition with a reasonable expectation of success in increasing the storage shelf-life and maintaining the maximum stable oxygen content in the composition, in view of the beneficial teachings of Taijin.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

Art Unit: 1654

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

NO CLAIMS ARE ALLOWED.

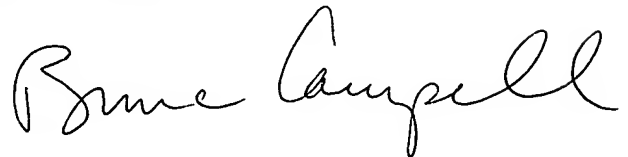
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Bruce Campbell can be reached on (571)272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Andrew D. Kosar, Ph.D.
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